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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/995,358      | 11/26/2001  | Jules Zecchino       | 2870/566            | 2755             |

7590

01/14/2002

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/995,358

Applicant(s)

JULES ZECCHINO ET AL

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

Examiner acknowledges receipt of paper number 2 filed 01/09/02.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wheeler (WO 97/32559).

Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel. The oil-based bi-liquid foam of Wheeler et al. comprises from 1% to 80% by weight of the total formulation. The composition of Wheeler et al. also comprises silicone oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol. Wheeler et al. teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase. Wheeler et al. teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate. Salts of cross-linked polymers of acrylic acid (carbomers), glyceryl polymethacrylates, or copolymers of polyoxyethylene/polyoxypropylene in mixtures with the previously listed surfactants may serve as gelling agents. Wheeler's composition (example 3) comprises citric acid and the composition is adjusted to pH 6.5 (less than pH 7) See page 3, paragraph 2 to page 5 paragraph 2. Wheeler anticipates the claims

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) and Collin et al. (US 5,667,789).

Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel. The oil-based bi-liquid foam of Wheeler comprises from 1% to 80% by weight of the total formulation. The composition of Wheeler also comprises silicone oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol. Wheeler teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase. Wheeler teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate. Salts of cross-linked polymers of acrylic acid (carbomers), glyceryl polymethacrylates, or copolymers of polyoxyethylene/polyoxypropylene in mixtures with the previously listed surfactants may serve as gelling agents. Wheeler's composition (example 3) comprises citric acid and the composition is adjusted to pH 6.5 (less than pH 7). See page 3, paragraph 2 to page 5 paragraph 2.

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However, Wheeler failed to teach alpha-hydroxy acids or beta-hydroxy acids as active agents. But Collin teaches oil-in-water cosmetic composition comprising salicylic acid, salicylic acid derivatives, silicone containing oil (cyclomethicone), octyl palmitate and the oils comprising 10% to 70% by weight of the total emulsion. Collin et al. further teaches the composition to comprise carboxyvinyl polymers and carbomers gelling agents in amounts of 0.1% to 10%.

Wheeler teaches pharmaceutical and cosmetic composition comprising bi-liquid foam that further comprises active ingredients, silicone oil, sulfonate salts, surfactants and gelling agents. Collin teaches cosmetic composition comprising salicylic acid active ingredient, silicone oil and gelling agents in an oil-in-water emulsion. Collin also teaches that the salicylic acid stabilizes oil-in-water emulsions. See column 1, line 7 to column 5, and line 2.

In the case where the compositions of prior art are used for the same purpose, in this instance, cosmetic, "it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Wheeler in the manner disclosed by Collin. One having ordinary skill in the art would have been motivated to prepare the composition of Wheeler et al. and incorporate the salicylic acid of Collin et al. wherein the salicylic acid is the active ingredient and further stabilizes the bi-liquid foam. The amount of the bi-liquid foam of the instant invention overlaps with amount of the bi-liquid form disclosed

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by Wheeler et al. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is not critical how a composition is made. The invention is obvious over the prior art in the absence of a showing of unexpected result over the prior art.

5. Claims 1, 2 and 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) and Collin et al. (US 5,667,789) in view of Clariant product brochure.

Wheeler and Collin are discussed in the preceding rejection. Although, Wheeler suggests ammonium sulfonate salt gelling agent, and Wheeler and Collin both teach the incorporation of gelling agent into the formulation, they failed to teach the specific gelling agent Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide. But the Clariant product brochure teaches Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide gelling agent for aqueous systems and thickening agent for oil-in-water emulsions. It would have been obvious to one having ordinary skill in the art at the time the invention was made and one motivated to prepare the composition of Wheeler and Collin to use the commercial gelling agent disclosed in the Clariant product brochure in the composition of the prior art.

Wheeler's composition is adjusted to pH 6.5, which is less than pH 7. The pH of the formulation claimed in the instant invention is an inherent property where it would be expected that similar compositions disclosed in the prior arts and the instant invention would have similar pH. Thus, in the absence of a showing of unexpected result over the prior art, the invention is not critical over the prior art.

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Applicants' cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374.

The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
January 10, 2002

THURMAN K. PAGE  
SUPERVISOR PATENT EXAMINER  
TECHNOLOGY CENTER 1600